From FDA/CDRH to help facilities implement MQSA

MammographyMatters

January/February 1996 Volume 3, Issue 1

From the Editor…

FDA will soon publish in the **Federal Register** *the proposed final MQSA regulations to replace the interim regulations now in effect. A 90-day period following publication will be allowed for public comment.*

We plan to mail the **Federal Register** *containing the proposed regulations to everyone on our mailing list as soon after publication as possible. Please read the portions in which you are interested and send your comments promptly to the address that will be provided in the* **Federal Register** *notice.*

All interested persons are encouraged to comment on the proposed final regulations so FDA may benefit from as wide a range of opinions and information as possible. After the comment period ends, FDA will review all comments received. The proposed regulations will then be revised as needed in response to these comments before final regulations are published.

On another note, we again urge you to send us your comments and suggestions for articles for **Mammography Matters.** *Contact us at:*

Mammography Matters, *FDA/CDRH (HFZ-240), 1350 Piccard Drive, Rockville, MD 20850, Fax: 301-594-3306*

Accreditation Bodies Play Vital Role in Implementing MQSA

FDA is now more than a year into implementing MQSA. Most efforts thus far have focused on program activities, with much of the credit going to the four accreditation bodies: the American College of Radiology (ACR) and the States of Arkansas, California, and Iowa. Although FDA certifies facilities, the accreditation bodies perform all the accreditation work and provide the information FDA uses to certify and decertify facilities.

The accreditation bodies are responsible for the initial assessment of various facets of facility performance. They inform FDA when a facility meets the accreditation standards, including passing clinical and phantom image reviews. FDA, in turn, sends facilities their certificates based on that information.

Accreditation bodies also continue to assess facilities through the reaccreditation process.

A major accomplishment of the accreditation bodies has been to increase the number of accredited facilities from the 4,600 that were accredited under the ACR's voluntary program to more than 10,000 in less than a year. The ACR standards that were once voluntary were adopted as interim MQSA standards and now apply to all facilities in the country. All four accreditation bodies helped make this possible.

> Most [MQSA] efforts thus far have focused on program activities, with much of the credit going to the four accreditation bodies.

The ACR and the state-based accreditation bodies each have a slightly different history with facility interaction. Compared with the ACR, the states have had a more direct, personal involvement through their periodic facility inspections under state mammography laws.

The following sections provide

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What's Inside

From the Director . . .

At this writing, FDA has inspected 7,110 of the 10,100 certified mammography facilities in the U.S. Because we consider our inspection program a joint effort with facility personnel, I wish to take this opportunity to share with you some of FDA's philosophy behind this program.

The annual inspection requirement is mandated by Congress through the Mammography Quality Standards Act. We've designed the program to allow facilities opportunities to improve practices and to come into compliance. Our goal is to work with you, not to be punitive. Because we want you to know our expectations, we'll continue to share with you our inspection procedures as they evolve.

We also want our inspection program to improve with time. In meeting this commitment, we will continue to modify the program as needed and send clarifications to our inspectors and facilities. And, to ensure consistency and minimize interpretation, we'll continue to keep our inspection questions as specific as possible.

Identifying problems early and assisting inspectors so they can do the best job possible are top priorities for us. Kay Chesemore, M.B.A., heads

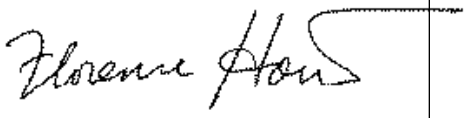
our active inspector quality assurance program to ensure these goals are met. The program includes inspector continuing education (yes, we require 15 continuing education units in mammography every 3 years, just like the rest of you!), surveillance (identification of early problems through review of inspections and audits), and resolutions of problems.

When we become aware of problems— such as when an inspector's sensitometer is not functioning properly or when inspection results are disputed—we work with all parties to address these concerns. We then institute procedures that may prevent recurrences of the same problem.

One important means for FDA to improve the inspection program is to obtain your advice. You can direct your suggestions and comments to us in several ways:

- *by calling our toll-free facility hot-line number, 800-838-7715;*
- *by writing to us at the FDA Quality Mammography Program, P.O. Box. 60057, Columbia, MD* 21045-6057; or
- *by writing to* **Mammography Matters** *at the address given at the end of the "From the Editor" column on page 1.*

We really believe the MQSA program is a partnership with all of you. Please work with us to improve the program!



Florence Houn, M.D., M.P.H.
Director, Division of Mammography Quality and Radiation Programs

Proposed Final MQSA Regulations: A Progress Report

The Mammography Quality Standards Act (MQSA) of 1992 requires that mammography facilities meet FDA quality standards and be accredited by an FDA-approved body to become FDA certified and operate lawfully. The MQSA program is now being carried out under interim regulations.

Soon we expect to publish in the *Federal Register* proposed final regulations that will set forth new, more detailed standards for both mammography facilities and accreditation bodies. This step is designed to solicit public comment. The proposal will be revised on the basis of comments received, and final regulations will be published about a year later.

In December 1993, Congress amended MQSA to permit FDA to issue interim regulations. The streamlined interim regulation process was necessary to meet the October 1, 1994, deadline for certification of all mammography facilities. FDA published the interim regulations for accreditation bodies and mammography facilities in December 1993 and amended the regulations in September 1994.

In a report accompanying the September 1994 amendments, Congress confirmed its intent that the interim regulations were to be only temporary. To achieve fully the goal of quality mammography, more comprehensive final regulations were to be developed. FDA has been drafting those final regulations since January 1994.

In addition to the expertise of its own personnel, FDA has received assistance from several sources in developing the regulations, including the National Mammography Quality Assurance Advisory Committee, equipment manufacturers, public comments received in response to the interim regulations, and experience gained during the initial months of the MQSA program. The advisory committee has been particularly helpful, devoting five of its meetings and 10 to 15 days to discussing the proposed regulations and providing FDA with advice.

When the proposed final regulations are published, we expect that a 90-day period will be allowed for public comment. Please refer to the "From the Editor" column on page 1 for additional information on this subject.

If Your Facility Moves, Inform Your Accreditation Body

To ensure that your facility receives copies of *Federal Register* notices and other correspondence from FDA, including *Mammography Matters*, it's absolutely essential that you inform your accreditation body of any changes in your facility's name or address. The only way FDA can change an address in its facility mailing list is if the facility's accreditation body provides the agency with this new information. The name on the address label must be that of the individual who signed your application for accreditation.

So, if you officially represent a facility (e.g., your mailing label has the name of your accreditation body printed on the upper right), don't send your new address to FDA or rely on the U.S. Postal Service to supply us with a change-of-address notice.

If, however, you're receiving *Mammography Matters* because you specifically asked to be on our mailing list, continue to send any address changes to our address listed at the end of the "From the Editor" column on page 1. If you're receiving the newsletter as an individual (and not as the official who signed the application for accreditation), your labels will not have the ACR or any of the three state accreditation bodies designated on the label.

Accreditation Bodies

Continued from page 1

an overview of each of our accreditation bodies, their history, and how they operate.

American College of Radiology

The ACR is a professional organization whose objectives are to advance the science of radiology, improve radiological services to patients, study the socioeconomic aspects of radiology practice, and encourage improved and continuing education for radiologists and allied health professionals.

John Curry
Executive Director
American College of Radiology

In the mid-1980s, FDA and the Conference of Radiation Control Program Directors identified serious problems with the quality of mammographic images through the Nationwide Evaluation of X-ray Trends (NEXT) study. As a result, the ACR created a task force and committee in 1986 to work on developing a voluntary accreditation program. At the same time, the American Cancer Society (ACS) was promoting early breast cancer detection through screening mammography. Because the ACS wanted to encourage women to have routine screening, but was concerned about image quality, it awarded a grant to the ACR to pilot test this new voluntary Mammography Accreditation Program (MAP). By mid-1987, the program had been developed and pilot tested, and the first applications for voluntary accreditation were accepted.

The goal of MAP was to ensure that ACR-accredited facilities provided high quality mammography services. The program featured feedback to facilities about ways to improve mammography quality. To ensure consistency in the evaluation process, the ACR developed an 8-hour required training program for both radiologist and physicist reviewers. Those who reviewed clinical and phantom images were evaluated quarterly for consistency on the basis of their pass/fail rate, disagreement rate, and timeliness. Facility quality was measured by clinical image quality, phantom image scores (correlated with dose), personnel qualifications and equipment specifications, and implementation of QC and QA programs.

The ACR also developed a Mammography Quality Control Manual that facilities could use as a "cookbook" style tool to maintain image quality. After publication of the manual in 1990, the rate of phantom and processor failure gradually decreased. Further, under a grant from the Centers for Disease Control and Prevention, the ACR developed educational programs for the various personnel involved in mammography.

Since the inception of MAP, the ACR has provided the ACS and other mammography referral agencies with a monthly list of ACR-accredited sites. (The ACS list includes all FDA-certified facilities, including those accredited by states.)

By 1993, when FDA issued the interim MQSA regulations, the ACR had accredited more than 4,600 facilities nationwide, and another 2,000 were in the process of being accredited. FDA approved the ACR as an accreditation body in March 1994. It also approved MAP, with minor modifications, converting the previously voluntary program to an accreditation program under MQSA. ACR continues to work with FDA and the other accreditation bodies in providing high quality mammography to American women.

John Curry, Executive Director of the ACR, says, "We are committed to the accreditation process, as it is one of the critical components of our nation's fight against breast cancer. Quality mammography will continue to receive our attention, as will other issues in the detection and treatment of breast cancer."

Arkansas

Arkansas' involvement in mammography began in 1989 when the state's General Assembly passed legislation requiring mammography facilities to be accredited annually by the Arkansas Department of Health (ADH). The goal of this program was to ensure that every woman in

Greta J. Dicus
Former Director
Division of Radiation Control and Emergency Management
Arkansas Department of Health

the state would have access to high quality mammography. At that time, Arkansas was one of only seven states in the U.S. to establish quality standards for mammography.

In 1992, ADH began accrediting mammography facilities throughout the state. A year later, ADH decided to apply for MQSA accreditation body status because of its accreditation experience and its positive working relationship with state facilities. It became an accreditation body in September 1994.

A cornerstone of the Arkansas program is clinical image review (CIR) by a group of seven highly qualified, board-certified volunteer radiologists who participate in a continuing CIR training program intended to ensure the highest possible level of CIR consistency. These radiologists, in addition to their formal CIR activities for the state, bring their knowledge and expertise to mammographers throughout Arkansas by working with a variety of professional organizations, including the state chapter of the ACR.

Facilities that apply to become accredited by ADH can complete the accreditation process within 6 weeks, if the phantom and clinical images pass their first review. (Arkansas requires a passing grade on the same eight CIR elements as the ACR.) However, of 44 Arkansas-accredited facilities, the failure rate for first clinical image review was 77 percent. The ADH, through its close association with Arkansas facilities, was able to work with these facilities to upgrade their mammography quality and reduce the expected final failure rate to 2 percent.

Arkansas regulations differ from those of MQSA, but during 1996, they will be modified to be identical to those of MQSA. The state is presently enforcing its regulations as though they are identical to MQSA

According to Greta Dicus, who until recently was the Director, Division of Radiation Control and Emergency Management, and is now with the Nuclear Regulatory Commision, "Accreditation has been challenging, but we are proud of the efforts we have taken to ensure quality mammography services for the women of Arkansas."

California

The California Radiological Health Branch (RHB) became involved in regulating mammography facilities and personnel several years before MQSA became effective. In 1990, California passed "Rules of Good Practice," which established statewide standards for mammography equipment. Legislation in 1991 and 1992 required annual facility inspections, approval of interpreting physicians, and certification of radiologic technologists as mammography technologists. Inspections included an equipment review to ensure phantom image quality and measurement of radiation dose. Planned regulatory changes will soon make California accreditation, quality standards, and interpreting physician requirements consistent with the interim regulations.

With the implementation of MQSA in 1994, California facilities faced additional requirements, including: (1) choosing either the California RHB or the ACR as their accreditation body, (2) undergoing clinical image reviews, (3) assuring

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Edgar D. Bailey
Chief
Radiologic Health Branch
California Department of Health Services

Accreditation Bodies

Continued from page 5

continuing education for personnel, and (4) having a system to review outcome data. If a California facility chooses the RHB as its accreditation body, the annual RHB registration fee includes the accreditation cost.

Edgar Bailey, Chief, RHB, California Department of Health Services, says, "RHB staff are familiar with all California mammography facilities because of the state requirements for equipment, personnel, and annual inspections. Therefore, RHB staff provide a hands-on approach to assist facilities in meeting all state and MQSA requirements."

One effect of MQSA in California is that, because of failure to meet clinical image review requirements, substandard facilities have ceased providing mammography services. On October 1, 1994, some 1,120 facilities were operating in California. During the past year, however, 159 facilities were closed. As of October 1, 1995, California had 961 FDA-certified facilities, 288 of which are accredited by RHB.

RHB helps achieve a high level of quality mammography for California women by working with the federally funded Breast and Cervical Cancer program and the Maternal and Multicultural Health program to coordinate personnel training, address access issues, and promote a statewide media campaign. Its role in this coordinated effort is to provide expertise related to mammography equipment and personnel. California's program also has identified a potential problem with mammography access, particularly in Asian and Hispanic communities. Further analysis is underway, and appropriate interventions are being planned.

Iowa

Iowa's mammography regulations, adopted in October 1992, closely paralleled those of the Health Care Financing Administration (HCFA). Yearly inspections of all mammography facilities have been conducted since that time, and approximately half of the facilities inspected have required reinspection because of noncompliances.

Donald A. Flater
Chief
Bureau of Radiological Health
Iowa Department of Public Health

With the implementation of MQSA on the horizon, the Iowa Department of Public Health (IDPH) submitted an application to FDA to become an accreditation body. In April 1994, FDA granted IDPH accreditation body status.

To meet the clinical image review requirement, the IDPH established a panel of five radiologists with strong mammography backgrounds to evaluate clinical images and establish evaluation criteria. Under the IDPH program, each set of clinical images is examined by at least two radiologists and then returned to the facility along with the radiologists' comments and a grade of pass or fail on the following eight elements: positioning, compression, exposure level, resolution, contrast, noise, film labeling, and artifacts.

The IDPH also has worked closely with the Iowa Society of Radiologic Technologists (ISRT) to develop the ISRT Mammography Training Program, which is available throughout Iowa. A representative from IDPH attends each program to answer participants' questions. In addition to this training program, the IDPH conducts MQSA-related outreach activities for other mammography groups throughout the state. This cooperative effort enables IDPH to provide mammography personnel with information that can be taken directly back to the facilities. IDPH has made a concerted effort to contain the costs of the accreditation program and to pass these cost savings on to the facilities.

Don Flater of IDPH tells us, "In Iowa, we take great pride in our mammography program, our mammography facilities, and our achievements in providing women with quality mammography."

Your Employer Identification Number (EIN): A Must for Reimbursement

Millions of Medicare claims are processed annually through some 80 Medicare payors. Because of the enormity of the task, processing is highly automated. To help ensure timely reimbursement for mammography claims under Medicare, FDA has agreed to provide the Health Care Financing Administration (HCFA) with the Employer Identification Number (EIN) for each mammography facility.

A facility cannot be reimbursed for a Medicare claim without a valid six-digit FDA Facility Identification Number (listed on the FDA certificate) for the facility plus the facility's name, address, and EIN. If any of these elements is missing or does not match those in HCFA's system files, the reimbursement process must be continued manually, a substantially slower process.

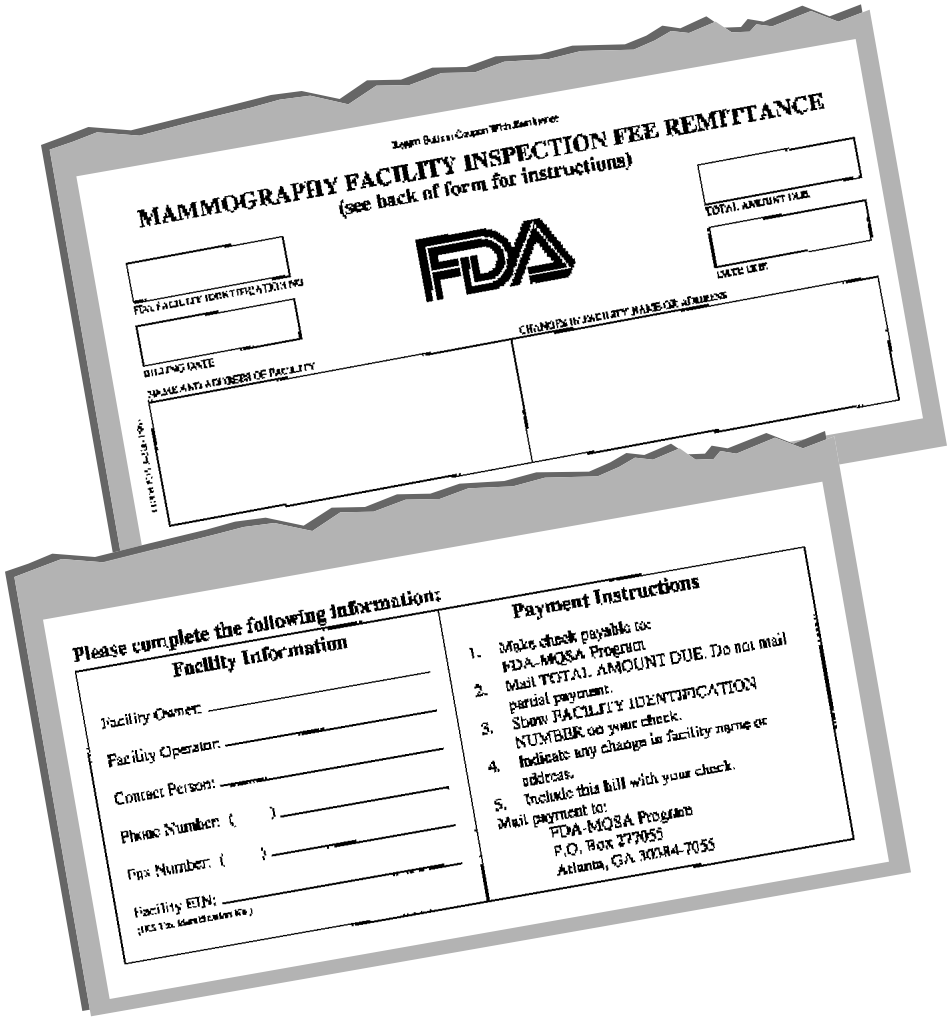
Therefore, we are requesting that you provide your EIN when you pay your mammography inspection fee and/or when you apply for accreditation or reaccreditation. The accreditation bodies will send this information to FDA.

Your facility's EIN should be available from the billing or business office that submits claims to the Medicare payor for mammography performed by the facility. If more than one EIN is associated with a facility, the correct number to report is the EIN submitted to the Medicare payor by the facility's billing or business office.

Every week, via electronic data transmittal, FDA provides HCFA with updated information on each certified facility's FDA Mammography Facility Identification Number, the facility's name and address, the effective and expiration dates of the facility's certificate, and the facility's EIN.

As stated in the box on page 3 of this issue of *Mammography Matters*, all facility name and address changes must be reported to the facility's accreditation body immediately so the accreditation body can update its records and transmit the changes to FDA. This is the only means by which FDA can change facility addresses in its database. Once entered, these changes are then automatically transmitted to HCFA with the next weekly data transmission.

Another EIN number you might need for completing your tax records is FDA's EIN, which is 53-0196965.



MQSA Highlights: 1993 to Present

FDA's Division of Mammography Quality and Radiation Programs (DMQRP), which is responsible for implementing MQSA, has been in existence for only a little more than 2 years. It began with a handful of people and has since grown to a staff of nearly 50. Some of the highlights of our MQSA activities and our accomplishments to date are listed below.

Authority to implement MQSA:

The Department of Health and Human Services gave FDA the authority to implement MQSA in June 1993. FDA then established DMQRP in the Center for Devices and Radiological Health to carry out the MQSA program

Program leadership:

Florence Houn, M.D., M.P.H., was named director of DMQRP in December 1993. She is also an instructor with The Johns Hopkins Oncology Center's Breast Surveillance Service.

Standards development:

FDA published interim final standards for mammography facilities and accreditation bodies in the December 1993 *Federal Register.* Proposed final standards, with a request for comment, are scheduled to be published in early 1996. Final standards will follow in about a year.

Advisory Committee:

FDA established the National Mammography Quality Assurance Advisory Committee, composed of 19 individuals—physicians, practitioners, and other health professionals—whose expertise includes a significant focus on mammography. Four of the members represent national breast cancer and consumer health organizations. We've met with the committee eight times to discuss standards developments and other issues of committee concern.

Accreditation bodies:

FDA has approved four MQSA accreditation bodies: the American College of Radiology (ACR) and the States of Iowa, California, and Arkansas.

Facility certification:

As of mid-February 1996, FDA had issued 9,922 certificates based on information supplied by the accreditation bodies. Of these, 9,560 are fully certified, and the remainder, which are in the process of being accredited or reinstated, are provisionally certified.

Database development:

Our DMQRP staff are developing a state-of-the-art database to track certification, inspection, and accreditation information and to allow us to assess the impact of MQSA.

Inspector training:

DMQRP has developed an MQSA training curriculum and, as of February 1996, had trained and certified approximately 220 inspectors. To become certified, inspectors must attend and pass a series of three 2-week courses. FDA awarded a contract for teaching Course I. Courses II and III are taught by members of our staff and guest instructors.

We held two teleconferences for inspectors—on December 7, 1994, and September 7, 1995—to address inspection questions and issues.

> The interim standards are having more than a symbolic effect [on mammography quality], because to become fully certified, many facilities have had to improve their practices.
>
> *— From the General Accounting Office Report to Congress on the initial impact of MQSA*

Inspections:

As of late February 1996, our inspectors had performed 7,265 inspections. The results of these inspections have been entered into our database.

State contracts for inspections:

FDA awarded contracts to 49 states and three other jurisdictions (District of Columbia, New York City, and Puerto Rico) to perform MQSA inspections. Because New Mexico chose not to contract with us, FDA personnel perform inspections in that state.

Inspection fees:

As required by MQSA, FDA analyzed the cost of performing inspections and determined how much to charge facilities to recoup those costs. The agency also developed a definition for "governmental entities," which are exempt from paying inspection fees. We designed a special form to be filled out by these entities to claim this exemption. Billing began in September 1995.

Compliance and enforcement:

With headquarters and field personnel in FDA's Office of Regional Affairs, DMQRP developed a compliance and enforcement program that reflects the need to ensure quality mammography while allowing adequate time for facilities to come into compliance.

- *Inspection levels:* FDA developed three levels of inspection findings to reflect the degree to which noncompliance would affect the quality of mammography offered.
- *Communication:* We mailed various documents to facilities and inspectors, explaining how to prepare for inspections, outlining the fee structure, and describing the three compliance levels and actions to take in response to inspection findings.

Outreach activities:

- *Newsletter:* We designed and published seven quarterly issues of *Mammography Matters* (including this issue) and also have developed a newsletter for inspectors.
- *Presentations and exhibits:* We staffed exhibits and gave presentations at more than 30 national and regional professional meetings.
- *Consumer brochure:* We assisted the Agency for Health Care Policy and Research in developing and distributing a mammography brochure for consumers.
- *Mammography Information Service:* In cooperation with the National Cancer Institute, we developed and implemented a system for providing names and locations of FDA-certified mammography facilities to consumers and health professionals by calling 1-800-4-CANCER.
- *Journal articles:* We authored articles and participated in interviews that have been published in more than a dozen professional journals.

Program evaluation:

- *Research:* We're performing research on inspection and certification data to better understand MQSA's impact on quality and availability of mammography services.
- *GAO report:* We collaborated with the General Accounting Office (GAO) in their study of the impact of MQSA. According to the October 1995 GAO Report, "...The interim standards are having more than a symbolic effect [on mammography quality], because to become fully certified, many facilities have had to improve their practices."

Q & A

Q & A is a regular column in **Mammography Matters.** *We welcome your questions and will publish answers to any that are of general interest. Send your questions to* **Mammography Matters,** *FDA/CDRH (HFZ-240), 1350 Piccard Drive, Rockville, MD 20850, Fax: 301-594-3306.*

Q What actions must a facility take before using a new mammography system on examinees?

A The facility should contact its accreditation body, then meet that body's requirements.

Q Are the requirements different if a facility already operating under a full certificate decides to purchase another mammography system?

A No. The facility must notify its accreditation body of the acquisition and comply with that body's requirements for new equipment.

Q What should I do when we plan to discontinue mammography at our facility?

A You should notify your accreditation body as soon as you plan to discontinue mammography. You should also mail your certificate to FDA as soon as possible after you discontinue mammography, along with a letter explaining why you are no longer going to perform mammography.

Q I am a technologist who had only 20 hours of training specifically in mammography on October 1, 1994, but I've used the year of experience alternative to qualify under MQSA. I'm looking ahead to October 1, 1996, when that alternative will no longer exist, and have chosen to meet the training requirement by bringing my total hours of mammography training up to at least 40.

Will the training I receive to meet the continuing education requirement of an average of 5 hours a year have to be in addition to the training I am receiving to meet the initial requirement, or can the same courses be used for both purposes?

A In your case, you should count the last 20 hours of the 40 toward the continuing education requirement.

As a general rule, however, we don't allow double counting of training for both initial and continuing education purposes. But, technologists who at first met the initial training requirement by using the experience alternative and now wish to maintain their status by receiving at least 40 hours of mammography training before October 1, 1996, are in a unique situation.

For this reason, we will permit such technologists to also count toward their continuing education any part of that 40 hours received after the date on which they satisfied the initial requirements using the experience alternative.

Q One of the initial MQSA requirements for interpreting physicians is to "have 40 hours of documented continuing medical education in mammography." Does this mean that even recent graduates of residency programs will have to earn 40 CME in mammography before they can begin to interpret independently?

A No, not if they received adequate training in mammography in their residency program. The regulations do not limit training to meet this requirement to formal CME courses. They also allow the use of residency training.

Thus, if the radiologist received at least 40 contact hours of training in mammography during residency, he or she meets this requirement. The 40 hours can include training in radiation physics, radiation effects, radiation protection, or mammography interpretation.

The training can be documented by the physician through a letter or, if the residency occurred before October 1, 1994, on FDA's suggested attestation form. Training also can be documented via a letter or other statement from the residency program.

Q & A

Q How long must mammography facilities keep their films?

A MQSA interim regulations require that you maintain records: (1) for a period of not less than 5 years or not less than 10 years if no additional mammograms of the examinee are performed at the facility, or longer if mandated by state or local law, or (2) until the examinee requests that the records be permanently transferred to a medical institution, to the examinee's physician, or to the examinee herself.

Thus, permanent transfer is allowed upon signature of the examinee. Release of obligation and liability are questions that must be addressed by state malpractice laws.

Q What does FDA accept as evidence that a technologist has met the initial training requirement in mammography?

A FDA will consider that a technologist has met the MQSA initial training requirement if the technologist has any ***one*** of the following:

- A California Mammography Radiologic Technology Certificate
- An Arizona Mammography Certificate
- An American Registry of Radiologic Technologists (ARRT) advanced certificate in mammography
- At least 40 hours of training in mammography
- Evidence of successful completion of the Medical Technology Management Institute (MTMI) 3-day mammography course for technologists.

These criteria are only guidance, not regulation. If a technologist does not meet any of the five criteria listed above, his or her training may still be adequate and will be evaluated individually.

Inspection Data Collection and Analysis

Data Collection

Inspection data are collected onsite by the inspector, who usually takes a laptop computer to the inspection site. The laptop is programmed to input inspection data and calculate on-the-spot results of some of the inspector's measurements. Instead of a laptop, the inspector may use printed data entry forms that are the same as those shown on the screens of the laptop when the inspection program is run.

Soon after the inspection, the inspector transmits the data via phone lines to a central computer at FDA headquarters where the data are analyzed.

Data Analysis

FDA Division of Mammography Quality and Radiation Program personnel periodically analyze the inspection data to determine in which areas facilities are doing well and which areas continue to be problems. Eventually, we hope to use the results of our analyses to improve the inspection process.

Data analysis is important for several reasons. First, by pinpointing the requirements that are most often cited, FDA can determine the most appropriate steps to take in helping facilities better understand their problems and how to solve them. Second, results of the analyses are used in our annual report to Congress and in our own evaluation of the MQSA program. In addition, we will collaborate with the National Cancer Institute to determine trends in breast cancer mortality in relation to improved mammography.

Dial It Right...

Accreditation, certification, or inspection information:
Mammography Quality Assurance Program
1-800-838-7715
Fax: 410-290-6351

Basic information packet (includes the Act, MQSA regulations, and most recent copy of *Mammography Matters*):
301-443-4190
Fax: 301-594-3306

To be added to the MQSA mailing list for periodic mailings or to report a change of address for our general mailing list:
Mammogrphy Matters
FDA/CDRH (HFZ-240)
1350 Piccard Drive
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Report official facility address changes to your accreditation body.

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Mammography Matters is a quarterly publication of the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health (CDRH), Food and Drug Administration. Its purpose is to help mammography facilities comply with the requirements of the Mammography Quality Standards Act of 1992. It is distributed to mammography facilities and other interested organizations and individuals.

Articles may be reproduced or adapted for other publications. Comments should be addressed to:

Mammography Matters
FDA/CDRH (HFZ-240)
1350 Piccard Drive
Rockville, MD 20850

Fax 301-594-3306.

Florence Houn, M.D., M.P.H., Director, DMQRP, CDRH

Carole Sierka, Managing Editor; Chief, Outreach Staff, DMQRP, CDRH

Mickie Kivel, Editor, DMQRP, CDRH

Other contributors: Cathy Akey, Roger Burkhart

Mammography Matters is a publication of the Food and Drug Administration, Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration (HFZ-240)
Center for Devices and Radiological Health
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Rockville, Maryland 20850

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